IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	AUDONNET et al.
Serial No.	:	09/677,672
Filing Date	:	October 2, 2000
For	:	ADJUVANT-CONTAINING DNA VECTORS
Examiner	:	Dave Nguyen
Art Unit	:	1635

745 Fifth Avenue, New York, NY 10151

EXPEDITED PROCEDURE
RESPONSE AFTER FINAL ACTION
UNDER 37 C.F.R. §1.116

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(Signature of person mailing paper or fee)

DECLARATION UNDER 37 C.F.R. §1.132

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
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Dear Sir:

I, Dr. Jean-Christophe Audonnet, declare and state that:

1. I make this declaration in connection with U.S. Application Serial No. 09/677,672. I am a co-inventor of this application and am familiar with its prosecution history, particularly as it pertains to the Final Office Action mailed April 23, 2004 and the rejection under 35 U.S.C. §103(a) of claims 1- as allegedly being unpatentable over any of Davis, Olsen or Crabb taken with any of Miles Inc., Lowell, Chavez, Gicquel or Wasmoen.

2. I am a citizen of France. As indicated on my attached *Curriculum vitiae* (Exhibit 1), I received a veterinary degree from Ecole Nationale Vétérinaire d'Alfort in 1980, a master's degree in molecular biology and genetics from University Montpellier in 1984, and a doctorate in molecular biology from Lyon University in 1989. I have also received a Certificate of Compared and Animal Immunology, a Certificate of Immunology and a degree in general virology. I have been employed by Merial, the assignee of this application, since September, 1997, and have served as Director of Molecular Biology and Immunology since May, 2001. From June, 1993 to September, 1997, I was employed as Head of the Molecular Biology and Genetic Recombination Units by Merial's predecessor company, Rhône Mérieux Lyon. In view of my education and experience, I consider myself to be an expert in the field to which this application pertains.

3. The April 23, 2004 Office Action alleges that the combination of any of Davis, Olsen or Crabb taken with any of Miles Inc., Lowell, Chavez, Gicquel or Wasmoen renders the instant invention obvious. The Office Action argues that Davis, Olsen and Crabb teach DNA vaccines, and that Miles Inc., Lowell, Chavez, Gicquel and Wasmoel teach the use of adjuvants including Carbopol®. All of Miles Inc., Lowell, Chavez, Gicquel and Wasmoel teach the use of these adjuvants in classical vaccines—vaccines that upon administration present an epitope or antigen to the immune system—or RNA vaccines, in which an entire or deleted genome is administered. In contrast, the presently pending claims relate to a DNA vaccine comprising (i) a naked DNA plasmid containing and expressing *in vivo* a polynucleotide encoding an antigenic polypeptide, wherein the antigenic polypeptide comprises an antigen of equine rhinopheumonia virus; and (ii) at least one adjuvant comprising carbopol.

4. In my expert opinion, one of skill in the art would not have applied the adjuvants used in Miles Inc., Lowell, Chavez, Gicquel and Wasmoel to the DNA vaccines of Davis, Olsen or Crabb with any expectation of success. Indeed, it was surprising and unexpected that the adjuvant of the instant claims functions to enhance immunogenicity of that which is expressed by the DNA vaccine, in this case, equine rhinopheumonia virus; and, there is no motivation from the cited documents to employ the adjuvants of the instant claims to DNA plasmid vaccines.

5. Attached as Exhibit 2 is a graph showing results obtained during experiments carried out under my direct knowledge, supervision and control in the ordinary course of business. These results were obtained by vaccinating horses with naked DNA containing and

expressing *in vivo* a polynucleotide encoding an antigenic polypeptide of EHV-1, both with and without the addition of Carbopol®. The graphs depicting the results from EHV-1 indicate that the general trend was that animals vaccinated with naked DNA and Carbopol® had higher levels of neutralizing antibodies and lower virus excretion than those vaccinated with naked DNA only. And, animals vaccinated with naked DNA and Carbopol® had a lower percentage of positive viral isolation by the end of the 21 day period.

6. The lower viral excretion resulting from the DNA and Carbopol® vaccine is especially important because equines tend to be housed in stables, and allowed to graze in large numbers, thereby placing individual animals in direct contact and/or close proximity with other equines, which significantly increases the chances of being exposed to EHV through the nasal droplets or mucus of infected equines. Consequently, the lowering of viral excretion levels by the presence of Carbopol® in the vaccine is of great importance.

7. In view of the foregoing, it is my opinion, as one of skill in the art, that there could have been no reasonable expectation of success for combining the use of adjuvants as taught by Miles Inc., Lowell, Chavez, Gicquel and Wasmoel with the DNA vaccines of Davis, Olsen or Crabb. Therefore, reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are requested.

8. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: _____ _____

Jean-Christophe Francis Audonnet, Ph.D.